

JUL 30 2009

5. 510(K) SUMMARY

Date Prepared: March 30, 2009

Trade Name: Echo™ Distal Access Catheter

Common Name: Percutaneous Catheter

Classification: Class II, 21 CFR 870.1250, Product Code DQY

Applicant: Nfocus™ Neuromedical
2191 E. Bayshore Road, Suite 100
Palo Alto, CA 94303
USA
Tel: 650-845-3064
Fax: 650-813-1869

Contact Person: Bob Founds
Director, Quality Assurance and Regulatory Affairs

Predicate Devices: Envoy Guiding Catheter, manufactured by Cordis Corporation
Neuron Intracranial Access System, manufactured by Penumbra, Inc.

Device Description:

The Echo™ Distal Access Catheter is a single-lumen, variable-stiffness catheter with an atraumatic tip at the distal end and a luer hub on the proximal end. The catheter shaft has a hydrophilic coating to reduce friction during use. Device dimensions and configuration are shown on the product label. The Echo Distal Access Catheter is compatible with introducer sheaths having an inner diameter of 6F or greater. A rotating hemostasis valve with side-arm adapter and a compatible guidewire are required, but not provided with the Echo catheter.

Intended Use:

The Echo Distal Access Catheter is indicated for the introduction of interventional and/or diagnostic devices and fluid infusion into the peripheral, coronary, and neuro vasculature. The indicated use is substantially equivalent to that of the legally marketed predicate devices.

Technological Characteristics of the Device Compared to the Predicate Device:

The Echo Distal Access Catheter uses similar technology, has similar intended use, functions, materials and method of operation as the following predicate device(s):

Device	Nfocus Neuromedical Echo Distal Access Catheter (Subject Device)	Cordis Endovascular Systems ENVOY Guiding Catheter	Penumbra Inc., Neuron Intracranial Access System
Intended Use	The Echo Distal Access Catheter is indicated for the introduction of interventional and/or diagnostic devices and fluid infusion into the peripheral, coronary, and neuro vasculature.	The Envoy Guiding Catheter is intended for use in the peripheral, coronary, and neurovasculature for the introduction of interventional / diagnostic devices.	The Neuron Intracranial Access System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.
Design:			
Outer Diameter (OD)	6 French	6 French	6 French
Inside Diameter (ID)	0.070"	0.070"	0.070"
Working Length	105cm	90-100cm	95-105cm
Catheter shaft	Transition in stiffness from hub to tip	Transition in stiffness from hub to tip	Transition in stiffness from hub to tip
Materials	Predominantly PTFE, Pebax, Stainless Steel, Hydrophilic coating	Predominantly PTFE, Nylon/polyurethane, Stainless Steel,	Stainless Steel, platinum, hydrophilic coating

Note: Materials in the predicate devices are not known with certainty. Material equivalence is demonstrated by *in vivo* performance tests and biocompatibility tests.

Summary of Studies:

In vitro bench testing and *in vivo* testing have been performed on the device materials and finished devices. Performance, sterilization and biocompatibility testing verified that the Echo Distal Access Catheter performs as designed and is suitable for its intended use.

Conclusion:

The data presented in this submission demonstrate that the Nfocus Neuromedical Echo Distal Access Catheter is substantially equivalent to the predicate devices identified in regards to device design, materials, and intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Nfocus™ Neuromedical
c/o Mr. Bob Founds
Director, Quality Assurance and Regulatory Affairs
2191 E. Bay Shore Road Suite 100
Palo Alto, Ca 94303

JUL 30 2009

Re: K090918
Trade/Device Name: Echo™ Distal Access Catheter
Common Name: Catheter, Percutaneous
Regulation Number: 21 CFR 870.1250
Regulatory Class: II
Product Code: DQY
Dated: July 16, 2009
Received: July 21, 2009

Dear Mr. Founds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

Page 2 – Mr. Bob Founds

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Bram D. Zuckerman', with a long horizontal flourish extending to the right.

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



4. INDICATIONS FOR USE STATEMENT

510(K) Number (if known): K090918

Device Name: Nfocus™ Neuromedical Echo™ Distal Access Catheter

Indications for Use:

The Nfocus Neuromedical Echo Distal Access Catheter Vessel is indicated for the introduction of interventional and/or diagnostic devices and fluid infusion into the peripheral, coronary, and neuro vasculature.

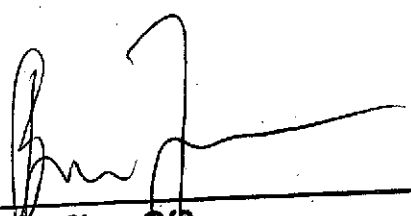
Prescription Use X
(21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K090918